PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	11 MAR 2005
Applicant's or agent's file reference: 031392PC	FOR FURTHER ACTION: See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/001800	21 December 2004	23 December 2003

International Patent Classification (IPC) or both national classification and IPC

Cl.[7] C07H 5/10, 13/12, 15/04, 11/04, 15/18; A61K 31/70, 31/7012, 31/7016, 31/7028; A61P 7/00, 7/02, 29/00, 35/00, 31/00, 43/00

Applicant

PROGEN INDUSTRIES LIMITED et al

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [X] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [X] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: **1, 3 (in part)**

because:

☐ the said international application, or the said claim Nos.

relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos.

are so unclear that no meaningful opinion could be formed *(specify)*:

The permutations and combinations of the various variables of the structural formula I of claim 1 give many classes of compounds that the specification does not provide support for. Claim 1 is also drafted so unclearly that the scope of the claim cannot be determined. A partial search was completed on claim 3.

☐ the claims, or said claims Nos.

are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. **1, 3 (in part)**

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**2, 11**	**YES**
	Claims	**1, 3-10, 12-14**	**NO**
Inventive step (IS)	Claims	**2, 11**	**YES**
	Claims	**1, 3-10, 12-14**	**NO**
Industrial applicability (IA)	Claims	**1-14**	**YES**
	Claims		**NO**

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 WO 1985/000973
D2 US 4459293
D3 WO 2003/038054
D4 Derwent Abstract Accession No 2000-100762/09
D5 Derwent Abstract Accession No 2001-337999/36
D6 Derwent Abstract Accession No 2000-116716/10
D7 WO 1993/024506
D8 WO 1997/018222
D9 Derwent Abstract Accession No 96-116981/12
D10 US 5700918
D11 Chemical Abstracts AN 140:314439
D12 Chemical Abstracts AN 141:54554
D13 Chemical Abstracts AN 138:82903
D14 Chemical Abstracts AN 133:267051
D15 Chemical Abstracts AN 131:322848
D16 Chemical Abstracts AN 129:107414

D11 and D12 are published after the priority date of the application. These documents may become relevant if the priority date of the application is found to be invalid at a later date.

D1 discloses substituted phenyl-1-thio(poly-O-sulfo)-α(or β)-D-glucopyranosides, cation salts thereof and their use as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes. This disclosure renders claims 1, 3, 4-10, 12 and 13 not novel and not inventive.

D2 discloses bis-[β-D-glucopyranosyl-1-thio (or sulfinyl or sulconyl)-arylene sulfate derivatives, the cation salts thereof, useful as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes. This disclosure renders claims 1, 3, 4-10, 12 and 13 not novel and not inventive.

D3 discloses compounds of Structures I–VI (see Figures 8-11) which anticipates claim 1 as presently drafted.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 1 is not clear with regard to the following:
   (i) The variable R has not been defined.
   (ii) It is not clear what can be included in this all encompassing substituent –"straight chain, cyclic, branched, substituted, heterocyclic, heteroatom substituted or unsubstituted alkyl, alkenyl, alkynyl, aryl, or heteroaryl"- at page 51 lines 13-14. A similar comment applies to the variable Y at page 52 lines 4-8.
   (iii) It is not clear how, when R_1 to R_6= unit I, is attached to the compound I. The phrase "attached through any position" does not give any indication of how this may be achieved.
   No clear meaning can be given to the scope of claim 1.

Claim 1 is not fully supported by the description with regards to the following:
(i) The definition of R_1 to R_6 is very broad and include many substituents that the specification provides no support for.
(ii) Each of R_1 to R_6 can be a structural unit I or II, this potentially claims oligo- and poly- saccharides. There is no support for this broad definition.
(iii) Each of R_7 to R_{11} can be a structural unit I or II, this potentially claims oligo- and poly- saccharides. There is no support for this broad definition.
(iv) The definitions of Z and X include many substituents that are not supported by the description.
(v) Tables 1-4 contain compounds which have no regards to the proviso at page 52 lines 13-14.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:Box V

D4 discloses sulfated galactose compounds (I) and their pharmaceutical preparation which anticipate claims 1, 3 and 4.

D5 discloses glucopyranose derivatives of formula (1) useful in the prevention and/or treatment of HIV infections, asthma, atopic dermatitis, and allergic and inflammatory disorders. This disclosure renders claims 1, 4-10 and 14 not novel and not inventive.

D6 discloses glucopyranose derivatives of formulae (I) useful in the treatment of HIV infection which anticipate claims 1, 3 and 4.

D7 discloses disaccharide derivatives of formula I or II and their use in modulating cell mediated immune responses eg for treating psoriasis, asthma, inducing tolerance to antigens. This disclosure renders claims 1, 4-10 and 12 not novel and not inventive.

D8 discloses oligosaccharides of formulae I and II with immunosuppressive and tolerogenic activity for modulating cell mediated immune responses especially inflammation eg for treating psoriasis, asthma, dermatitis. Some of the starting materials also anticipate claims 1 and 3 (see, for example, Figure 1A). This disclosure renders claims 1, 3, 4-10 and 12 not novel and not inventive.

D9 discloses mono- or di- saccharide derivatives of formulae (IIIa)-(IIId) that anticipates claims 1 and 3.

D10 discloses a moranoline derivative of formula (I) used for treating inflammation, immunopathy, viral infection and cancer etc which anticipates claims 1, 4-10, 12 and 14.

D13 discloses a galactopyranosyl derivative as a pharmaceutical which anticipates claims 1, 3 and 4.

D14 discloses a galactopyranosyl derivative with anti-HIV activity which anticipates claims 1, 3 and 4.

D15 discloses a galactopyranosyl derivative with anti-inflammatory activity which anticipates claims 1, 4-10 and 12.

D16 discloses a galactopyranosyl derivative with anti-inflammatory activity which anticipates claims 1 and 4.

Claims 1-14 have industrial applicability.